REMARKS

Status of the Application

Claims 8, 10 and 17-19 are under current consideration, and stand rejected.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Rejection under 35 U.S.C. § 101

The Examiner has rejected claims 8, 10 and 17-19 under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a specific or substantial asserted utility or a well-established utility. Applicant respectfully traverses the rejection. However, Applicant believes the rejection has been overcome in light of the arguments below.

Specifically, the Examiner has stated that the asserted utility for the claimed transgenic mice does not appear to be specific and substantial. The Examiner has based the rejection on the evidence of record allegedly not providing a correlation between the phenotypes exhibited by the claimed mice and any disease or disorder. The Examiner further asserts that the evidence of record has failed to provide a correlation between any platelet-activating factor receptor related disease or disorder and the phenotypes claimed. Applicants respectfully disagree. However, although Applicants submit that the correlation has been provided, **and** is well-established in the relevant art, Applicants do not believe that the assertion of such a correlation is necessary for the establishment of utility and for the patentability of the claimed transgenic mice. For the reasons set forth below, Applicants submit that the Examiner's rejection of the claims for lack of utility is improper.

Claims 8, 10 and 17-19 are drawn to a transgenic mouse whose genome comprises a disruption in the nucleotide sequence set forth in SEQ ID NO:1, wherein the mouse exhibits an increased latency to respond to a thermal stimulus in the hot plate test, and an increased time spent in the central region in the open field test, and to a method of making the transgenic mouse. Applicants have asserted in the specification several potential uses for the transgenic knockout mouse, and such uses of transgenic knockout mice are well accepted within the art. See, for example, page 3, lines 20-28, page 4, lines 16-26 and page 19, line 4 through page 20, line 3, of the specification.

Applicants submit that in order to satisfy the utility requirements set forth in 35 U.S.C. § 101, the specification must assert a specific and substantial utility that is credible to a skilled

artisan, or the utility of the claimed invention must be apparent to the skilled artisan. See MPEP § 2107. Applicants submit that the instant specification satisfies these requirements.

The instant specification has demonstrated that disruption of SEQ ID NO:1 in a mouse results in a specific phenotype. In particular, the transgenic mice whose genomes comprise the disruption exhibit a higher pain threshold and a decreased propensity toward anxiety, as characterized by their performance in well-established behavioral tests – the hot plate test and the open field test (See page 52, line 17 through page 53, line 10 of the specification). The phenotypic parameters of the transgenic mice were evaluated in controlled studies, and the performance of the knockout mice was reported relative to wild-type control mice, *i.e.* with the same background and environmental conditions.

It is generally accepted in the art that transgenic knockout mice, such as those described in and claimed by the instant application, represent a valuable tool for determining the function of genes. In the present case, the transgenic mouse described in the instant specification would be accepted by the skilled artisan as a model for the role of the platelet-activating factor receptor gene represented by SEQ ID NO:1. Applicants' disclosure related to the phenotypes of the transgenic mice has established that this gene plays a role in the conditions or disorders of anxiety and pain sensitivity, as noted above. More particularly, the transgenic mice as claimed represent a precise example of antagonizing the target gene, and reveal to the skilled artisan that antagonizing or decreasing expression of the target gene provides a reasonable treatment method for anxiety and/or pain. The value of such an *in vivo* model would be immediately recognized by a person skilled in the art. This is supported by the trend to produce such transgenic mice with disruptions in virtually every gene.

In light of the role of the target gene in anxiety and pain sensitivity demonstrated by Applicants' disclosure, the skilled artisan would recognize a variety of uses for the transgenic mice related to these conditions or disorders. Applicants submit that the transgenic mice, as an *in vivo* model for the treatment of anxiety and/or pain sensitivity, provide a valuable tool for defining the role that the disrupted gene plays in these conditions. The transgenic mice would also be useful for determining the specificity of agents intended to target the nucleotide sequence of SEQ ID NO:1, or other therapeutic targets. Further, Applicants assert that the transgenic mice could be used for the development of therapeutic agents or other treatments intended to ameliorate or affect anxiety and/or pain sensitivity, which treatments would mimic the disruption produced in the

claimed transgenic mice. The skilled artisan could use these mice to test known compounds used in the treatment of anxiety or pain related disorder, such as anti-psychotic agents or analgesic agents, which target a protein or system other than the nucleotide sequence comprising SEQ ID NO:1. More particularly, the transgenic mice could be used to screen such agents to determine whether these compounds would act additively or synergistically with an agent that targets the nucleotide sequence comprising SEQ ID NO:1 to affect anxiety or pain sensitivity in order to improve current therapies for these conditions.

Applicants have asserted in the specification several specific and substantial uses for the claimed transgenic mice. Further, in light of the art-recognized value of and demand for transgenic knockout mice, the asserted utilities are among many that are well-established and credible to the skilled artisan.

In view the arguments set forth above, Applicants believe the rejection of the claims under 35 U.S.C. § 101 is improper, and respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 8, 10 and 17-19 under 35 U.S.C. § 112, first paragraph, because one skilled in the art would allegedly not know how to use the claimed invention as a result of the alleged lack of either a specific or substantial asserted utility or a well-established utility set forth in the above utility rejection. Applicants respectfully traverse the rejection. However, for the reasons set forth above in response to the utility rejection, Applicants submit that the rejection under 35 U.S.C. § 112, first paragraph, is improper. Therefore, Applicants respectfully request withdrawal of the rejection.

It is believed that the claims are currently in condition for allowance, and notice to that effect is respectfully requested. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1271 under Order No. R-17.

Respectfully submitted,

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